REMARKS/ARGUMENTS

Claims 75-94 are pending. By this Amendment, claims 38, 40, 41, 43, 45-48, 50-52 and 54-74 have been cancelled in favor of new claims 75-94. Reconsideration in view of the above amendments and the following remarks is respectfully requested.

Claims 40, 41 and 57 were rejected under 35 U.S.C. § 102(b) over Corbin et al. (U.S. Patent No. 3,252,623). In as much as this reject may apply to the new claims, it is respectfully traversed. Specifically, independent claim 75 includes subject matter of cancelled claims 38 and 45. In particular, claim 75 is directed to a system for the infusion of a pharmacological solution comprising, *inter alia*, and elastomeric container which elastomeric container was previously recited in claim 45 which was not rejected based on Corbin et al. under 35 U.S.C. § 102(b). In fact, the Office Action indicates in paragraph 6 (discussed later) that Corbin et al. is silent on the pumping device comprising an elastomeric container.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 43 and 54-56 were rejected under 35 U.S.C. § 103(a) over Corbin et al. in view of Franetzki et al. (U.S. Patent No. 4,270,532). This rejection is respectfully traversed since the subject claims have been cancelled. In as much as the subject matter of these cancelled claims appear in various ones of the newly presented claims, the rejection is respectfully traversed in that these claims depend from claim 75, which is patentable for reasons discussed above. Moreover, Franetzki et al. does not make up for the deficiencies of Corbin et al., and nor was it relied upon to teach such subject matter.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 45-48 and 50-52 were rejected under 35 U.S.C. § 103(a) over Corbin et al. in view of Kanai et al. (U.S. Patent No. 6,367,502). This rejection is respectfully traversed.

Claim 75 is directed to a system for the infusion of a pharmacological solution in a patient, comprising an elastomeric container for containing a pharmacological solution and for generating a flow of said pharmacological solution from said container to a catheter insertable in the body of the patient; a valve arrangement to vary said flow; and a command and control device operationally connected to said valve arrangement to command a pulsed actuation of said valve arrangement, said flow being determined by the number of actuations of said valve arrangement per unit time.

Neither Corbin et al. nor Kanai et al. teach or suggest this subject matter. For example, neither Corbin et al. nor Kanai et al. teach or suggest the combination of an elastomeric container for containing a pharmacological solution and for generating a flow of said pharmacological solution from said container to a catheter insertable into the body of the patient.

Corbin et al. teaches a pulse generator arranged to provide a series of pulses corresponding to the rate of delivery of drops intended to be achieved. The flow is an intermittent flow generated by a number of drops and the flow rate is controlled by adjusting the number of drops.

Kanai et al. teaches the control of infusion flow rate by selectively pressing and shutting a plurality of flow control tubes. The flow is substantially continuous and flow rate control is based on the selection of tubes with certain characteristics.

The claimed elastomeric container with pulsed actuation results in an infusion system having no drops. Applicants discovered that the elastomeric container exerts a pressure on the solution that has a substantially constant value (see dependent claim 92). Thus, the accuracy of the dosing is guaranteed or improved in substantially time-sharing mode even if the flow is not a dripping flow. Moreover, claim 75 has a simple construction with respect to Corbin et al. and

Kanai et al. (without use of a dropper control or a plurality of controlling tubes), with the same accuracy, or even better accuracy as explained below.

In particular, Applicants respectfully submit their belief that the claimed system improves the accuracy of the dosage of the solution. Firstly, in the claimed system of flow generation does not substantially or principally depend on the location of the solution container, while in Corbin et al. the container location can be a factor strongly influencing the drop generation and thus the accuracy of the dosage. Secondly, in the claimed system the flow rate is adjusted on the basis of pulse actuation (or valve frequency) and not from the variation of a structural characteristic (essentially the shape and size of the fluid passage section) of the fluid passage. In Kanai et al., the control depends on such a variation actuated by the selection of tubes whereby the error, especially the percentage error when the flow range is lower (fine dosage) and a section of the fluid passage is thus narrow, is inevitably greater.

Stated differently, the system in claim 75 provides improved accuracy with regard to flow rate compared to the devices of Corbin et al. and Kanai et al. in that, the flow rate is less dependent from the height at which the solution container is located whereby the inaccuracy due to unpredictable location of the container is prevented. In addition, the regulation based on the number of actuations of the valve on the same transport element (tube) can be more accurate than a regulation based on the selection of number of different transport elements (each having its construction error that normally increases in percentage with the narrowing of the tubes) as in Kanai et al.

Moreover, Applicants respectfully disagree with the statement in point 6, next to last paragraph of the Office Action. In particular, the elastomeric container in claim 75 and the flow generating means of Corbin et al. (i.e. placing the solution container at a level higher than the

patient level) cannot be considered equivalent ways of generating a flow of a solution, in particular when the control of the flow is operated by commanding a pulsed actuation of a valve arrangement. First, the way of generating the flow is different in that in Corbin et al. the pulses generate the drops while the system in claim 75 does not result in dripping flow. Second, when a valve arrangement is pulse-actuated, a fluidic disturbance is generated through the system, which disturbance can be mitigated by the presence of an elastomeric pressurized container which exerts a sort of damping action. Therefore, the system of claim 75 overcomes a drawback due to the adoption of the pulse-actuated valve to control infusion flow. See also page 3, lines 13-23 of the original PCT publication which states that the elastomeric container exerts pressure on the pharmacological solution at a value such as to overcome load losses present in the infusion circuit and in the solenoid valve.

Reconsideration and withdrawal of the rejection are respectfully request.

Claims 58 and 59 were rejected under 35 U.S.C. § 103(a) over Corbin et al. in view of Crankshaw et al. (U.S. Patent No. 4,741,732). Claims 89 and 90 correspond to claims 58 and 59, and are patentable by virtue of their dependence on claim 75. Crankshaw et al. does not make up for the deficiencies noted above, and was only relied upon for its teachings of a rechargeable battery.

Reconsideration and withdrawal of the rejection are respectfully request.

In view of the above amendments and remarks, Applicants respectfully submit that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith

(or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4017-41.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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